

K081794

JUL 10 2008

807.92(a)(5)

Intended Use(s)
510(k) Summary

The following 510(k) summary has been prepared pursuant to requirements specified in 21CFR§807.92(a).

807.92(a)(1)

Submitter Information

Carri Graham
Anson Group
11460 N. Meridian St., Ste. 150
Carmel, IN 46032
Phone: (317) 569-9500 x 103
Facsimile: (317) 569-9520

Contact Person: Carri Graham

Date: June 3, 2008

807.92(a)(2)

Trade Name: 7340 Ultrasound System

Common Name: Ultrasound Imaging System

Classification Name(s): Ultrasonic pulse Doppler imaging system 892.1550
Ultrasonic pulsed echo imaging system 892.1560

Classification Number: 90IYN, 90IYO

807.92(a)(3)

Predicate Device(s)

K040596, K052805 & K060827	7300 (MyLab30)	Esaote, S.p.A.
K051837 & K060827	6100 (MyLab90)	Esaote, S.p.A.

807.92 (a)(4)

Device Description

The 7340 is a portable ultrasound system used to perform diagnostic general ultrasound studies. Its primary modes of operation are: B-Mode, M-Mode, Multi View (MView), Doppler, Color Flow Mapping, Amplitude Doppler (AD), Tissue Velocity Mapping (TVM) and Tissue Enhancement Imaging (TEI). The 7340 is equipped with a LCD Color Display. The full alphanumeric keyboard allows complete on-screen data entry of patient information and on-screen annotations. The 7340 can drive phased (PA), convex (CA), linear array (LA), Doppler probes and BiScan probes. The 7340 is equipped with an internal Hard Disk and with a DVD-RW disk drive that can be used for image storage. Data can also be stored directly to external archiving media (hard-disk, PC, server) via a LAN/USB port. Optional accessory devices available for the 7340 include an S-VHS video recorder; a monochrome or color page printer and a mobile trolley equipped with an insulation transformer.

807.92(a)(5)

Intended Use(s)

Esaote's Model 7340 is a compact ultrasound system used to perform diagnostic general ultrasound studies including Cardiac, Transesophageal, Peripheral Vascular, Neonatal Cephalic, Adult Cephalic, Small organ, Musculoskeletal (Conventional and Superficial), Abdominal, Fetal, Transvaginal, Transrectal, Pediatric, Laparoscopic, Intraoperative Abdominal, and Other Urologic. The system provides imaging for guidance of biopsy and imaging to assist in the placement of needles and catheters in vascular or other anatomical structures as well as peripheral nerve blocks in Musculoskeletal applications.

807.92(a)(6)

Technological Characteristics

	7340 (This submission)	7300 (K040596, K052805 and K060827)	6100 (K051837 and K060827)	Acuson P10 (K063761)
Electrical Safety	IEC60601-1	IEC60601-1	IEC60601-1	EN60601-1
Ultrasound Safety	Track 3 (Acoustic Output Display)	Track 3 (Acoustic Output Display)	Track 3 (Acoustic Output Display)	Unknown
Indication for Use				
• Cardiac	YES	YES	YES	YES
• Transesophageal Cardiac	YES	YES	YES	Unknown
• Peripheral Vascular	YES	YES	YES	Unknown
• Neonatal Cephalic	YES	YES	YES	Unknown
• Adult Cephalic	YES	YES	YES	YES
• Small organ	YES	YES	YES	Unknown
• Musculoskeletal (conventional & superficial)	YES	YES	YES	Unknown
• Abdominal	YES	YES	YES	YES
• OB/Fetal	YES	YES	YES	YES
• Transvaginal	YES	YES	YES	Unknown
• Transrectal	YES	YES	YES	Unknown
• Pediatric	YES	YES	YES	YES
• Intraoperative	YES	YES	YES	Unknown
Laparoscopic	YES	NO	YES	Unknown
Other: Urological	YES	YES	YES	Unknown
Probe Technology				
• Phased Array	YES	YES	YES	YES
• Linear Array	YES	YES	YES	Unknown
• Convex Array	YES	YES	YES	Unknown
• Doppler Probes	YES	YES	YES	Unknown
• BiScan Probes	YES	YES	YES	Unknown
Modes of operation	2D, M-Mode, MView, PW, CW, CFM, Amplitude Doppler, TEI, TVM	2D, M-Mode, MView, PW, CW, CFM, Amplitude Doppler, TEI, TVM	2D, M-Mode, PW, CW, CFM, Amplitude Doppler, TEI	B, Color Doppler, Combined (B + Color Doppler)
Imaging Frequencies	2.5, 3.5, 4.0, 5.0, 6.6, 7.5, 8.0, 10, 12, 15, 18 MHz	2.5, 3.5, 4.0, 5.0, 6.6, 7.5, 8.0, 10, 12, 15, 18 MHz	1 – 16 MHz	2-4 MHz
CFM/Doppler Frequencies	2.0, 2.5, 2.9, 3.3, 4.0, 5.0, 6.6, 8.0 MHz	2.0, 2.5, 2.9, 3.3, 4.0, 5.0, 6.6, 8.0 MHz	2 – 12 MHz	Unknown
Biopsy Guidance	YES	YES	YES	Unknown
• Biopsy Intended Uses	General Purpose,	General Purpose,	General Purpose,	Unknown

	7340 (This submission)	7300 (K040596, K052805 and K060827)	6100 (K051837 and K060827)	Acuson P10 (K063761)
	Transrectal, Transvaginal, Intraoperative	Transrectal, Transvaginal, Intraoperative	Transrectal, Transvaginal Intraoperative	
• Biopsy Line Depth marker	1 cm	1 cm	1 cm	Unknown
Needle Guide Angle	ABS15: 45° ABS33: 90° ABS523: 45° ABS621: 25° 35°	ABS15: 45° ABS33: 90° ABS523: 45° ABS621: 25° 35°	ABS15: 45° ABS523: 45° ABS621: 25° 35°	Unknown
Display type	LCD	LCD	CRT	LCD
Display Standard	SVGA	SVGA	SVGA	Unknown
Digital Archival Capabilities	YES	YES	YES	Unknown
DICOM Classes: Media Storage, Storage SCU, Worklist, MPPS and Storage Commitment, Print	YES	YES	Media Storage, Storage SCU	Unknown
VCR / Page Printer	YES	YES	YES	Unknown
M&A Capabilities	Cardiac, Vascular, Urological, Gynaecological, OB and general purpose measurements	Cardiac, Vascular, Urological, Gynaecological, OB and general purpose measurements	Cardiac, Vascular, OB and general purpose measurements	Unknown
Advanced Tools	3D/4D, VPan, Stress Echo, Strain and Strain Rate analysis, Intima-Media Thickness	3D/4D, VPan, Stress Echo, Strain and Strain Rate analysis, Intima-Media Thickness	3D/4D, Stress Echo, Strain and Strain Rate analysis, Intima-Media Thickness	Unknown
Weight	portable: about 11 kg with battery installed with trolley: 46 kg	portable: 10 kg with trolley: 40 kg	120 kg	Unknown
Dimensions	portable position: 38.2 (w) x 16.5 (h) x 49 (d) cm use position: 38.2 (w) x 43 (h) x 49 (d) cm with trolley: 50 (w) x 133 (h) x 51 (d) cm	portable position: 35.5 (w) x 14 (h) x 49 (d) cm use position: 35.5 (w) x 41 (h) x 49 (d) cm with trolley: 50 (w) x 130 (h) x 51 (d) cm	60(w) x 160 (h) x 120(d) cm	54mm (h) x 97mm (w) x 137mm (l)
Internal Lithium Ion Battery	Yes	No	No	Yes



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Esaote, S.p.A
% Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services LLC
1394 25th Street NW
BUFFALO MN 55313

JUL 10 2008

Re: K081794
Trade/Device Name: 7340 Ultrasound System
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: II
Product Code: ITX, IYN, and IYO
Dated: June 24, 2008
Received: June 25, 2008

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the 7340 Ultrasound System, as described in your premarket notification:

Transducer Model Number

PA230
PA122
LA332
LA523
C5-2
CA123

CA531
CA631
2 CW
5 CW
EC1123
TRT33
TEE022
TEE122
IOE323
LP323
BS230
BC431

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This determination of substantial equivalence is granted on the condition that prior to shipping the first device, you submit a postclearance special report. This report should contain complete information, including acoustic output measurements based on production line devices, requested in Appendix G, (enclosed) of the Center's September 30, 1997 "Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers." If the special report is incomplete or contains unacceptable values (e.g., acoustic output greater than approved levels), then the 510(k) clearance may not apply to the production units which as a result may be considered adulterated or misbranded.

The special report should reference the manufacturer's 510(k) number. It should be clearly and prominently marked "ADD-TO-FILE" and should be submitted in duplicate to:

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, Maryland 20850

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed

predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>

If you have any questions regarding the content of this letter, please contact Paul Hardy at (240) 276-3666.

Sincerely yours,



fn Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure(s)

Indications for Use

510(k) Number (if known):

Device Name: 7340 Ultrasound System

Esaote's Model 7340 is a compact ultrasound system used to perform diagnostic general ultrasound studies including Cardiac, Transesophageal, Peripheral Vascular, Neonatal Cephalic, Adult Cephalic, Small organ, Musculoskeletal (Conventional and Superficial), Abdominal, Fetal, Transvaginal, Transrectal, Pediatric, Laparoscopic, Intraoperative Abdominal, and Other Urologic. The system provides imaging for guidance of biopsy and imaging to assist in the placement of needles and catheters in vascular or other anatomical structures as well as peripheral nerve blocks in Musculoskeletal applications.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Page 1 of 1


(Division Sign-Off)

Division of Reproductive, Abdominal and
Radiological Devices


510(k) Number

K081794

Mod.7340

Clinical Application	Mode of Operations									
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined [3]	TVM	Tissue Enhancement Imaging (TEI)	Other (specify)
Ophthalmic										
Fetal	N	N	N		N	N	N		N	5, 6, 7, 8, 9, 10
Abdominal	N	N	N	N	N	N	N		N	5, 6, 7, 8, 9
Intraoperative (Abdominal)	N	N	N		N	N	N		N	5, 6, 8, 9, 13
Intraoperative Neurological										
Pediatric	N	N	N	N	N	N	N		N	5, 6, 8, 9, 13
Small Organ [1]	N	N	N		N	N	N		N	4, 5, 6, 8, 9, 13
Neonatal Cephalic	N	N	N	N	N	N	N		N	5, 6, 8, 9
Adult Cephalic	N	N	N	N	N	N	N		N	6, 8, 9
Cardiac [2]	N	N	N	N	N	N	N	N	N	4, 6, 7, 8, 9, 11, 12
Transesophageal (Cardiac)	N	N	N	N	N	N	N	N	N	4, 6, 9, 11, 12
Transesophageal (Non Cardiac)										
Transrectal	N	N	N		N	N	N		N	5, 6, 8, 9, 13
Transvaginal	N	N	N		N	N	N		N	5, 6, 8, 9
Transurethral										
Intravascular										
Peripheral Vascular	N	N	N	N	N	N	N		N	5, 6, 7, 8, 9, 10, 12, 13
Laparoscopic	N	N	N		N	N	N		N	5, 6, 8, 9, 13
Musculo-skeletal Conventional (including Nerve Blocking)	N	N	N		N	N	N		N	4, 5, 6, 8, 9, 13
Musculo-skeletal Superficial (including Nerve Blocking)	N	N	N		N	N	N		N	4, 5, 6, 8, 9, 13
Other (Urological)	N	N	N		N	N	N		N	5, 6, 8, 9

- [1] Small Organs includes Breast, Thyroid and Testicles
 [2] Cardiac is Adult and Pediatric
 [3] Combined modes are: B + M + PW + CW + CFM + PD
 [4] CMM
 [5] MView
 [6] 3D
 [7] 4D
 [8] VPan
 [9] XView
 [10] QIMT
 [11] Stress
 [12] Strain
 [13] TP View


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 Division of Reproductive, Abdominal and
 Radiological Devices
 510(k) Number K081794

Clinical Application	Mode of Operations									
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined [3]	TVM	Tissue Enhancement Imaging (TEI)	Other (specify)
Opthalmic										
Fetal										
Abdominal	P	P	P	P	P	P	P		P	6, 8, 9
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric										
Small Organ [1]										
Neonatal Cephalic										
Adult Cephalic	P	P	P	P	P	P	P		P	6, 8, 9
Cardiac [2]	P	P	P	P	P	P	P	P	P	4, 6, 8, 9, 11, 12
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Endoscopic										
Musculo-skeletal Conventional (including Nerve Blocking)										
Musculo-skeletal Superficial (including Nerve Blocking)										
Other (Urological)										

The PA230 probe was previously cleared
via K040596 & 071996

- [1] Small Organs includes Breast, Thyroid and Testicles
 [2] Cardiac is Adult and Pediatric
 [3] Combined modes are: B + M + PW + CW + CFM + PD
 [4] CMM
 [5] MView
 [6] 3D
 [7] 4D
 [8] VPan
 [9] XView
 [10] QIMT
 [11] Stress
 [12] Strain
 [13] TP View

(Division Sign-Off)

Division of Reproductive, Abdominal and
Radiological Devices

510(k) Number

K081794

Clinical Application	Mode of Operations									
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined [3]	TVM	Tissue Enhancement Imaging (TEI)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric	P	P	P	P	P	P	P		P	6, 8, 9
Small Organ [1]										
Neonatal Cephalic	P	P	P	P	P	P	P		P	6, 8, 9
Adult Cephalic										
Cardiac [2]	P	P	P	P	P	P	P	P	P	4, 6, 8, 9, 11, 12
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular	P	P	P	P	P	P	P		P	6, 8, 9, 12
Laparoscopic										
Musculo-skeletal Conventional (including Nerve Blocking)										
Musculo-skeletal Superficial (including Nerve Blocking)										
Other (Urological)										

The PA122 probe was previously cleared via K040596

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- [10]
- [11]
- [12]
- [13]

Small Organs includes Breast, Thyroid and Testicles
 Cardiac is Adult and Pediatric
 Combined modes are: B + M + PW + CW + CFM + PD
 CMM
 MView
 3D
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 VPan
 XView
 QIMT
 Stress
 Strain
 TP View

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Division of Reproductive, Abdominal and Radiological Devices

510(k) Number

K081794

Clinical Application	Mode of Operations									
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined [3]	TVM	Tissue Enhancement Imaging (TEI)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric	N	N	N		N	N	N		N	5, 6, 8, 9, 13
Small Organ [1]	N	N	N		N	N	N		N	4, 5, 6, 8, 9, 13
Neonatal Cephalic										
Adult Cephalic										
Cardiac [2]										
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular	N	N	N		N	N	N		N	5, 6, 8, 9, 10, 12, 13
Laparoscopic										
Musculo-skeletal Conventional (including Nerve Blocking)	N	N	N		N	N	N		N	4, 5, 6, 8, 9, 13
Musculo-skeletal Superficial (including Nerve Blocking)	N	N	N		N	N	N		N	4, 5, 6, 8, 9, 13
Other (Urological)										

The LA332 probe to be cleared via this submission

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- [11]
- [12]
- [13]

Small Organs includes Breast, Thyroid and Testicles
 Cardiac is Adult and Pediatric
 Combined modes are: B + M + PW + CFM + PD
 CMM
 MView
 3D
 4D
 VPan
 XView
 QIMT
 Stress
 Strain
 TP View

(Division Sign-Off)

Division of Reproductive, Abdominal and Radiological Devices

510(k) Number

K081794

Clinical Application	Mode of Operations									
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined [3]	TVM	Tissue Enhancement Imaging (TEI)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric	P	P	P		P	P	P		P	5, 6, 8, 9, 13
Small Organ [1]	P	P	P		P	P	P		P	4, 5, 6, 8, 9, 13
Neonatal Cephalic										
Adult Cephalic										
Cardiac [2]										
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular	P	P	P		P	P	P		P	5, 6, 8, 9, 10, 12, 13
Laparoscopic	P	P	P		P	P	P		P	4, 5, 6, 8, 9, 13
Musculo-skeletal Conventional (including Nerve Blocking)	P	P	P		P	P	P		P	4, 5, 6, 8, 9, 13
Musculo-skeletal Superficial (including Nerve Blocking)	P	P	P		P	P	P		P	4, 5, 6, 8, 9, 13
Other (Urological)										
The LA523 probe was previously cleared via K040596 & 071996										

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[11]
[12]
[13]

Small Organs Includes Breast, Thyroid and Testicles
 Cardiac is Adult and Pediatric
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 3D
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 Stress
 Strain
 TP View

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Division of Reproductive, Abdominal and
 Radiological Devices

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Clinical Application	Mode of Operations									
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined [3]	TVM	Tissue Enhancement Imaging (TEI)	Other (specify)
Ophthalmic										
Fetal	N	N	N		N	N	N		N	5, 6, 8, 9, 10
Abdominal	N	N	N		N	N	N		N	5, 6, 8, 9
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric	N	N	N		N	N	N		N	5, 6, 8, 9
Small Organ [1]										
Neonatal Cephalic	N	N	N		N	N	N		N	5, 6, 8, 9
Adult Cephalic										
Cardiac [2]										
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular	N	N	N		N	N	N		N	5, 6, 8, 9, 12
Laparoscopic										
Musculo-skeletal Conventional (including Nerve Blocking)										
Musculo-skeletal Superficial (including Nerve Blocking)										
Other (Urological)										

The C5-2 is to be cleared via this submission

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- [12]
- [13]

Small Organs includes Breast, Thyroid and Testicles
 Cardiac is Adult and Pediatric
 Combined modes are: B + M + PW + CFM + PD
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 4D
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 Strain
 TP View

(Division Sign-Off)

Division of Reproductive, Abdominal and
 Radiological Devices

510(k) Number

K081794

Clinical Application	Mode of Operations									
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined [3]	TVM	Tissue Enhancement Imaging (TEI)	Other (specify)
Opthalmic										
Fetal										
Abdominal										
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric	P	P	P		P	P	P		P	5, 6, 8, 9
Small Organ [1]	P	P	P		P	P	P		P	4, 5, 6, 8, 9
Neonatal Cephalic	P	P	P		P	P	P		P	5, 6, 8, 9
Adult Cephalic										
Cardiac [2]	P	P	P		P	P	P		P	4, 5, 6, 8, 9
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular	P	P	P		P	P	P		P	5, 6, 8, 9, 12
Endoscopic										
Musculo-skeletal Conventional (including Nerve Blocking)	P	P	P		P	P	P		P	4, 5, 6, 8, 9
Musculo-skeletal Superficial (including Nerve Blocking)	P	P	P		P	P	P		P	4, 5, 6, 8, 9
Other (Urological)										

The CA123 probe was previously cleared via K023255 & 071996

- [1] Small Organs includes Breast, Thyroid and Testicles
 [2] Cardiac is Adult and Pediatric
 [3] Combined modes are: B + M + PW + CFM + PD
 [4] CMM
 [5] MView
 [6] 3D
 [7] 4D
 [8] VPan
 [9] XView
 [10] QIMT
 [11] Stress
 [12] Strain
 [13] TP View

(Division Sign-Off)

Division of Reproductive, Abdominal and Radiological Devices

510(k) Number

K081794

Clinical Application	Mode of Operations									
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined [3]	TVM	Tissue Enhancement Imaging (TEI)	Other (specify)
Ophthalmic										
Fetal	N	N	N		N	N	N		N	5, 6, 8, 9, 10
Abdominal	N	N	N		N	N	N		N	5, 6, 8, 9
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric	N	N	N		N	N	N		N	5, 6, 8, 9
Small Organ [1]										
Neonatal Cephalic										
Adult Cephalic										
Cardiac [2]										
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular	N	N	N		N	N	N		N	5, 6, 8, 9, 12
Laparoscopic										
Musculo-skeletal Conventional (including Nerve Blocking)	N	N	N		N	N	N		N	4, 5, 6, 8, 9
Musculo-skeletal Superficial (including Nerve Blocking)	N	N	N		N	N	N		N	4, 5, 6, 8, 9
Other (Urological)	N	N	N		N	N	N		N	5, 6, 8, 9

The CA531 probe is to be cleared via this submission

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- [2]
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Small Organs includes Breast, Thyroid and Testicles
 Cardiac is Adult and Pediatric
 Combined modes are: B + M + PW + CFM + PD
 CMM
 MView
 3D
 4D
 VPan
 XView
 QIMT
 Stress
 Strain
 TP View

(Division Sign-Off)

Division of Reproductive, Abdominal and
 Radiological Devices

510(k) Number

R081794

Clinical Application	Mode of Operations									
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined [3]	TVM	Tissue Enhancement Imaging [TEI]	Other (specify)
Ophthalmic										
Fetal	N	N	N		N	N	N		N	5, 6, 8, 9, 10
Abdominal	N	N	N		N	N	N		N	5, 6, 8, 9
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric	N	N	N		N	N	N		N	5, 6, 8, 9
Small Organ [1]										
Neonatal Cephalic										
Adult Cephalic										
Cardiac [2]										
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular	N	N	N		N	N	N		N	5, 6, 8, 9, 12
Laparoscopic										
Musculo-skeletal Conventional (including Nerve Blocking)	N	N	N		N	N	N		N	4, 5, 6, 8, 9
Musculo-skeletal Superficial (including Nerve Blocking)	N	N	N		N	N	N		N	4, 5, 6, 8, 9
Other (Urological)	N	N	N		N	N	N		N	5, 6, 8, 9

The CA631 probe is to be cleared via this submission

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Small Organs includes Breast, Thyroid and Testicles
 Cardiac is Adult and Pediatric
 Combined modes are: B + M + PW + CFM + PD
 CMM
 MView
 3D
 4D
 VPan
 XView
 QIMT
 Stress
 Strain
 TP View

(Division Sign-Off)

Division of Reproductive, Abdominal and Radiological Devices

510(k) Number

K081794

Clinical Application	Mode of Operations									
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined [3]	TVM	Tissue Enhancement Imaging (TEI)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric										
Small Organ [1]										
Neonatal Cephalic										
Adult Cephalic										
Cardiac [2]				P						
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional (including Nerve Blocking)										
Musculo-skeletal Superficial (including Nerve Blocking)										
Other (Urological)										

The 2CW probe was previously cleared via K982444 & 052805

- [1] Small Organs includes Breast, Thyroid and Testicles
 [2] Cardiac is Adult and Pediatric
 [3] Combined modes are:
 [4] CMM
 [5] MView
 [6] 3D
 [7] 4D
 [8] VPan
 [9] XView
 [10] QIMT
 [11] Stress
 [12] Strain
 [13] TP View

(Division Sign-Off)

Division of Reproductive, Abdominal and Radiological Devices

510(k) Number

K081794

Clinical Application	Mode of Operations									
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined [3]	TVM	Tissue Enhancement Imaging (TEI)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric										
Small Organ [1]										
Neonatal Cephalic										
Adult Cephalic										
Cardiac [2]										
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular				P						
Laparoscopic										
Musculo-skeletal Conventional (including Nerve Blocking)										
Musculo-skeletal Superficial (including Nerve Blocking)										
Other (Urological)										
The 5CW probe was previously cleared via K982444 & 052805										

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Small Organs includes Breast, Thyroid and Testicles
 Cardiac Is Adult and Pediatric
 Combined modes are:
 CMM
 MView
 3D
 4D
 VPan
 XView
 QIMT
 Stress
 Strain
 TP View


 (Division Sign-Off)

Division of Reproductive, Abdominal and
 Radiological Devices
 510(k) Number K081794

Clinical Application	Mode of Operations									
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined [3]	TVM	Tissue Enhancement Imaging (TEI)	Other (specify)
Ophthalmic										
Fetal	N	N	N		N	N	N		N	5, 6, 8, 9, 10
Abdominal										
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric										
Small Organ [1]										
Neonatal Cephalic										
Adult Cephalic										
Cardiac [2]										
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)										
Transrectal	N	N	N		N	N	N		N	5, 6, 8, 9
Transvaginal	N	N	N		N	N	N		N	5, 6, 8, 9
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional (including Nerve Blocking)										
Musculo-skeletal Superficial (including Nerve Blocking)										
Other (Urological)	N	N	N		N	N	N		N	5, 6, 8, 9

The EC1123 probe is to be cleared via this submission

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Small Organs includes Breast, Thyroid and Testicles
 Cardiac is Adult and Pediatric
 Combined modes are: B + M + PW + CFM + PD
 CMM
 MView
 3D
 4D
 VPan
 XView
 QIMT
 Stress
 Strain
 TP View

(Division Sign-Off)

Division of Reproductive, Abdominal and Radiological Devices

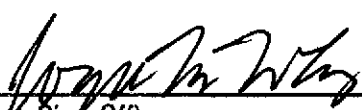
510(k) Number

K081794

Clinical Application	Mode of Operations									
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined [3]	TVM	Tissue Enhancement Imaging (TEI)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric										
Small Organ [1]										
Neonatal Cephalic										
Adult Cephalic										
Cardiac [2]										
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)										
Transrectal	N	N	N		N	N	N		N	5, 6, 8, 9, 13
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional (including Nerve Blocking)										
Musculo-skeletal Superficial (including Nerve Blocking)										
Other (Urological)	N	N	N		N	N	N		N	5, 6, 8, 9, 13
The TRT33 probe is to be cleared via this submission										

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Small Organs Includes Breast, Thyroid and Testicles
 Cardiac is Adult and Pediatric
 Combined modes are: B + M + PW + CFM + PD
 CMM
 MView
 3D
 4D
 VPan
 XView
 QIMT
 Stress
 Strain
 TP View


 (Division Sign-Off)

Division of Reproductive, Abdominal and
 Radiological Devices

510(k) Number

K081794

Clinical Application	Mode of Operations									
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined [3]	TVM	Tissue Enhancement (maging (TEI)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric										
Small Organ [1]										
Neonatal Cephalic										
Adult Cephalic										
Cardiac [2]										
Transesophageal (Cardiac)	P	P	P	P	P	P	P	P	P	4, 6, 9, 11, 12
Transesophageal (Non Cardiac)										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional (including Nerve Blocking)										
Musculo-skeletal Superficial (including Nerve Blocking)										
Other (Urological)										

The TEE022 probe was previously cleared via K040596

- [1] Small Organs includes Breast, Thyroid and Testicles
 [2] Cardiac is Adult and Pediatric
 [3] Combined modes are: B + M + PW + CW + CFM + PD
 [4] CMM
 [5] MView
 [6] 3D
 [7] 4D
 [8] VPan
 [9] XView
 [10] QIMT
 [11] Stress
 [12] Strain
 [13] TP View

(Division Sign-Off)

Division of Reproductive, Abdominal and Radiological Devices

510(k) Number

K081794

Clinical Application	Mode of Operations									
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined [3]	TVM	Tissue Enhancement Imaging (TEI)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric										
Small Organ [1]										
Neonatal Cephalic										
Adult Cephalic										
Cardiac [2]										
Transesophageal (Cardiac)	P	P	P	P	P	P	P	P	P	4, 6, 9, 11, 12
Transesophageal (Non Cardiac)										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional (including Nerve Blocking)										
Musculo-skeletal Superficial (including Nerve Blocking)										
Other (Urological)										
The TEE122 probe was previously cleared via K070803										

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 CMM
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 3D
 4D
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 XView
 QIMT
 Stress
 Strain
 TP View

(Division Sign-Off)

Division of Reproductive, Abdominal and
 Radiological Devices

510(k) Number

K081794

Clinical Application	Mode of Operations									
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined [3]	TVM	Tissue Enhancement Imaging (TEI)	Other (specify)
Ophthalmic										
Fetal										
Abdominal	P	P	P		P	P	P		P	5, 6, 8, 9, 13
Intraoperative (Abdominal)	P	P	P		P	P	P		P	5, 6, 8, 9, 13
Intraoperative Neurological										
Pediatric	P	P	P		P	P	P		P	5, 6, 8, 9, 13
Small Organ [1]	P	P	P		P	P	P		P	4, 5, 6, 8, 9, 13
Neonatal Cephalic										
Adult Cephalic										
Cardiac [2]										
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular	P	P	P		P	P	P		P	5, 6, 8, 9, 12, 13
Laparoscopic										
Musculo-skeletal Conventional (including Nerve Blocking)	P	P	P		P	P	P		P	4, 5, 6, 8, 9, 13
Musculo-skeletal Superficial (including Nerve Blocking)	P	P	P		P	P	P		P	4, 5, 6, 8, 9, 13
Other (Urological)										

The IOE323 probe was previously cleared via K052805

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Small Organs includes Breast, Thyroid and Testicles
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 CMM
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 XView
 QIMT
 Stress
 Strain
 TP View

(Division Sign-Off)

Division of Reproductive, Abdominal and Radiological Devices

510(k) Number

K081794

Clinical Application	Mode of Operations									
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined [3]	TVM	Tissue Enhancement Imaging (TEI)	Other (specify)
Ophthalmic										
Fetal										
Abdominal	P	P	P		P	P	P		P	5, 6, 8, 9, 13
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric										
Small Organ [1]										
Neonatal Cephalic										
Adult Cephalic										
Cardiac [2]										
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic	P	P	P		P	P	P		P	5, 6, 8, 9, 13
Musculo-skeletal Conventional (including Nerve Blocking)										
Musculo-skeletal Superficial (including Nerve Blocking)										
Other (Urological)										
The LP323 probe was previously cleared via K051837										

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Small Organs includes Breast, Thyroid and Testicles
 Cardiac is Adult and Pediatric
 Combined modes are: B + M + PW + CFM + PD
 CMM
 MView
 3D
 4D
 VPan
 XView
 QIMT
 Stress
 Strain
 TP View

(Division Sign Off)

Division of Reproductive, Abdominal and
 Radiological Devices

510(k) Number

K081794

Clinical Application	Mode of Operations									
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined [3]	TVM	Tissue Enhancement Imaging [TEI]	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric										
Small Organ [1]										
Neonatal Cephalic										
Adult Cephalic										
Cardiac [2]	P	P	P	P	P	P	P	P	P	4, 6, 7, 8, 9, 11, 12
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional (including Nerve Blocking)										
Musculo-skeletal Superficial (including Nerve Blocking)										
Other (Urological)										

The BS230 probe was previously cleared via K060827

- [1] Small Organs includes Breast, Thyroid and Testicles
 [2] Cardiac is Adult and Pediatric
 [3] Combined modes are: B + M + PW + CW + CFM + PD
 [4] CMM
 [5] MView
 [6] 3D
 [7] 4D
 [8] VPan
 [9] XView
 [10] QIMT
 [11] Stress
 [12] Strain
 [13] TP View

(Division Sign-Off)

Division of Reproductive, Abdominal and Radiological Devices

510(k) Number

K081794

Clinical Application	Mode of Operations									
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined [3]	TVM	Tissue Enhancement Imaging (TEI)	Other (specify)
Ophthalmic										
Fetal	P	P	P		P	P	P		P	5, 6, 7, 8, 9, 10
Abdominal	P	P	P		P	P	P		P	5, 6, 7, 8, 9
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric										
Small Organ [1]										
Neonatal Cephalic										
Adult Cephalic										
Cardiac [2]										
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular	P	P	P		P	P	P		P	5, 6, 7, 8, 9, 12
Laparoscopic										
Musculo-skeletal Conventional (including Nerve Blocking)										
Musculo-skeletal Superficial (including Nerve Blocking)										
Other (Urological)										

The BC431 probe was previously cleared via K060827

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Small Organs Includes Breast, Thyroid and Testicles
 Cardiac is Adult and Pediatric
 Combined modes are: B + M + PW + CFM + PD
 CMM
 MView
 3D
 4D
 VPan
 XView
 QIMT
 Stress
 Strain
 TP View

(Division Sign-Off)

Division of Reproductive, Abdominal and Radiological Devices

510(k) Number

K081794